REMARKS/ARGUMENTS

Claims 1, 6, 8-21, 25-43 and 45-61 are under examination in the application. The Office Action mailed on August 14, 2008, includes the following rejections:

1. Claims 1, 6, 8-21, 25-43, and 45-61 are rejected under 35 U.S.C. 112.

2. Claims 1, 6, 8-21, 25-43, and 45-61 are again rejected under 35 U.S.C. § 103(a).

Claims 1, 6, 8-21, 25-43, and 45-61 are again rejected under 35 U.S.C. 112, first paragraph, written description requirement.

The Office Action rejected claims 1, 6, 8-21, 25-43 and 45-61 under 35 U.S.C. § 112, first paragraph base on the assertion that the claims contains subject matters that was not described in the written description sufficiently to convey a skilled artisan that the inventors were in possession of the present invention. Applicants respectfully disagrees such assertion.

The Applicants assert that the subject matter of the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the claims provide an enveloped pharmaceutical composition having an immediate release composition and an extended release composition. The first active in contact with a carrier available for immediate release of guaifenesin with over 80% of the first active is released within 60 minutes. The second active phenylephrine is disposed on a bead for extended release where over 80% of the second active is released between 90 minutes and 6 hours. The second active is disposed on the bead in three or more layers and an extended release coating.

The specification provides a structure in the form of a pharmaceutical composition that is an enveloped by an extended release coating. The pharmaceutical composition includes a first immediate release active agent with a carrier and a second extended release active agent disposed on a bead. The specification also provides the function of the pharmaceutical composition in releasing over 80% of the first active agent within 60 minutes and releasing the over 80% of the

second active is released between 90 minutes and 6 hours. The skilled artisan would clearly recognize that the inventors had at the time the application was filed, possession of the claimed invention. Furthermore, the pharmaceutical compositions and release profiles are described in detailed in the specification, specific examples and guidance of sufficient, relevant, identifying characteristics are provided throughout the specification.

As a result, Applicants assert that the specification fully complies with the written description sufficiently to convey a skilled artisan that the Applicants were in possession of the present invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis").

The instant application provides a description of sufficient, relevant, identifying characteristics, including the structure of a pharmaceutical composition having a first immediate release active agent with a carrier and at least 3 layers of a second extended release active agent disposed on a bead that is enveloped by an extended release coating. The specification also describes the release profile of the composition with over 80% of the first active agent within 60 minutes and over 80% of the second active released between 90 minutes and 6 hours. Thus providing sufficient, relevant, identifying characteristics to convey a skilled artisan that the Applicants were in possession of the present invention.

The Applicants assert that the subject matter of the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The Examiner is reminded that not everything necessary to practice the invention need be disclosed, in fact, what is well known is best omitted. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991).

The Applicants assert that the subject matter of the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The skilled artisan would readily

know and understand the term enveloped; however the instant specification (e.g., paragraph [0025]) provides details of what "enveloped" means in the present Application, e.g., the term "enveloped pharmaceutical" means a capsule, a suppository, a gel cap, a softgel, a lozenge, a sachet or even a fast dissolving wafer. As used herein the term "carrier" is used to describe a substance, whether biodegradable or not, that is physiologically acceptable for human or animal use and may be pharmacologically active or inactive. The present specification provides numerous examples throughout, e.g., paragraph [0081] capsule shells and processes; Paragraph [0082] discloses four different levels of sustained release coating amounts were added; Paragraph [0085] discloses the dissolution rate of the phenylephrine that is accelerated when combined with Gauifenesin DC; Paragraph [0086] discloses the stability of capsules; Paragraph [0088] discloses Formula I, a batch of immediate release first active, e.g., guaifenesin for use with the enveloped formulation; Paragraph [0089], discloses Formula II, a batch of immediate release guaifenesin for use with the enveloped formulation; Paragraph [0090] discloses Formula III; Paragraph [0091] discloses Formula IV; and Paragraph [0092] discloses Formula V. Furthermore, specific enveloped pharmaceutical are disclosed, e.g., Paragraph [0094] disclosed a formulation for immediate release of a first active and extended release of a second active in an enveloped formulation, in a gelcap; Paragraph [0095] disclosed a formulation for immediate release of a first active and extended release of a second active in an enveloped formulation, in a suppository; Paragraph [0096] disclosed an effervescent tablet for immediate release of a first active and extended release of a second active in an enveloped formulation, in an effervescent tablet; and Paragraph [0097] disclosed an immediate release of a first active and extended release of a second active in an enveloped formulation one may add in a caplet. Similarly, numerous active agents are disclosed in the instant application, e.g., Paragraph [0098] summarizes some of the first and second actives in the table. As such , the Applicants assert that the subject matter of the claims are described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Furthermore, the specification provides numerous examples and Applicants disagree that the specification has "very limited examples." Applicants assert that examples are not necessary to fulfill the requirements of 35 U.S.C. § 112, first paragraph. In fact, possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of

the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas, which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. See, e.g., Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description "inquiry is a factual one and must be assessed on a case-by-case basis").

Applicants assert that what is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d at 1384, 231 USPQ at 94. See also Capon v. Eshhar, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005)("The 'written description' requirement must be applied in the context of the particular invention and the state of the knowledge... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution."). If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met. See, e.g., Vas-Cath, 935 F.2d at 1563, 19 USPQ2d at 1116; Martin v. Johnson, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in ipsis verbis [i.e., "in the same words"] to be sufficient").

Applicants also disagree with the assertion that the instant specification is "a wish or plan for obtaining the invention." As stated above the instant application provides numerous example and teachings and conveys to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

Applicants also disagree with Office Action's assertion of the need for step-plus-function language. The claims of the instant invention provide an enveloped pharmaceutical composition having an immediate release composition and an extended release composition. The first active in contact with a carrier available for immediate release with over 80% of the first active is released within 60 minutes. The second active is disposed on a bead for extended release selected from the group consisting of a decongestant, an antihistamine, an antitussive and mixtures thereof where over

80% of the second active is released between 90 minutes and 6 hours. The second active is disposed on the bead in three or more layers and an extended release coating. The written description in the specification links the release profiles to a materials (i.e., the bead, the carrier and the coating) and one skilled in the art would not know what structures or materials result in the claimed release profiles.

The Applicants assert that the claims fully comply with the written description requirement of 35 U.S.C. § 112, first paragraph and the claims are described in the written description sufficiently to convey a skilled artisan that the inventors were in possession of the present invention. Accordingly, Applicants respectfully request withdrawn all 35 U.S.C. § 112 rejections.

Claims 1, 6, 8-21, 25-43, and 45-61 are again rejected under 35 U.S.C. § 103(a)

The Office Action rejected claims 1, 6, 8-21, 25-43 and 45-61 under 35 U.S.C. § 103(a) as being unpatentable over Devane, et al., U.S. Patent No. 6,228,398 (Devane), in view of Dang, et al., U.S. Patent No. 6,462,094 (Dang) and Davis et al., U.S. Patent Application No. 2003/0049318 ("Davis"). Applicants submit that the references, either alone or in any combination, fail to meet the standard of rejection under 35 U.S.C. § 103.

Applicants submit that the references, either alone or in any combination, fail to meet the standard of rejection under 35 U.S.C. § 103 because the combination fails to teach every element of the present invention, there is no suggestion to combine reference teachings as proposed and there is no reasonable expectation of success. See MPEP § 2143; *In re Vacek*, 947 F.2d 488 (Fed. Cir.1991). "The prior art must suggest the desirability of the claimed invention." MPEP § 2143.01.

First, Applicants submit that the combination fail to teach every element of the present invention. The instant invention provides that the first active in contact with a carrier available for immediate release with over 80% of the first active is released within 60 minutes. The combination fails to teach this release. Devane teaches the immediate release only provides 50% of the first active in about 2 hours. Devane's extended, pulsate release only achieves 50% release in about 6 hours. Dang teaches a conventional tablet prepared by well-known conventional tabletting techniques that includes phenylephrine tannate and guaifenesin. Dang does not teach a first active

available for immediate release and a second active for extended release that are released during the required timeframes and does not provide the claimed release profile. The addition of Dang fails to teach any manner to achieve the claim release. Devane fails to add the missing preparation of the release profiles as claimed. The combination of Devane and Dang does not teach each and every element of the present Application. Dang fails to teach a first active in contact with a carrier and a second active is disposed on a bead for extended release. The addition of Davis does not cure these deficiencies. Davis teaches a drug product having two portions both of which contain guaifenesin. Davis teaches a compressed bi-layer tablet with an immediate release formulation of guaifenesin and a delayed release matrix formulation of guaifenesin, Davis does not teach an enveloped formulation that combines a first active of guaifenesin on a carrier and a second active of phenylephrine on a carrier.

The combination of Devane and Dang and Davis fails to teach each and every element of the present Application. Specifically, a first guaifenesin active available for immediate release, having over 80% of the first active released within 60 minutes; and a second phenylephrine active for extended release, wherein the first active is disposed on a carriers and the second active is disposed on a bead, wherein the second active comprises three or more layers of the second active agent and an extended release coating and wherein over 80% of the second active is released between 90 minutes and 6 hours. The combination fails to establish a *prima facie* case of obviousness.

Second, Applicants assert that there are no expectation of success nor motivations to combine because the proposed combination of the references would change the principle of operation of the prior art invention being modified and are not sufficient to render the claims *prima facie* obvious. See, MPEP Section 2143.01(V). There is no likelihood of success or motivation to combine because the combination would yield the combination unsatisfactory for the desired function. Devane's release is **substantially delayed**, and Devane prefers the second active to be almost completely delayed for at least two hours i.e., a pulsed manner (Col. 10 Line 52-64). This means that there are little to no drug available in-between the two pulses. Thus, the combination of references would result in a pharmaceutical composition that releases two active ingredients in a **pulsed, bimodal** way where the active ingredients are not consistently present in a subject due to the need of preventing drug tolerance. The present invention provides a

extended-release of the active ingredients. Accordingly, the combination of references fails to establish a *prima facie* obviousness.

For the reasons stated above, Applicants respectfully submit that claims 1, 6, 8-21, 25-43 and 45-61 are not obvious over Devane, Dang and Davis, therefore, allowable under 35 U.S.C. § 103(a) and respectfully request the withdrawal of the rejection under 35 U.S.C. § 103.

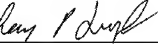
Conclusion

Claims 1, 6, 8-21, 25-43 and 45-61 are pending in the above-identified Application. Withdrawal of the objections and rejections and an early Notice of Allowance are earnestly requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

Dated: October 14, 2008

Respectfully submitted,



Chainey P. Singleton
Reg. No. 53,598
ATTORNEY FOR APPLICANTS

Customer No. 34,725
Chalker Flores, LLP
2711 LBJ FRWY, Ste. 1036
Dallas, TX 75234
214.866.0001 Telephone
214.866.0010 Facsimile